

Ronnie Smith and Linda Smith v. Ford Motor Company, et al. Defendants

AFFIDAVIT OF MARK A. ROBERTS, M.D., Ph.D., M.P.H., M.Ed., F.A.C.O.E.M.

1. I make this Affidavit in support of Defendant Ford Motor Company for a motion to preclude Dr. Hammar's opinions regarding every occupational and bystander exposure to asbestos above background as contributing to the development of Mr. Smith's mesothelioma. The opinions I have expressed herein are held to a reasonable degree of medical and scientific certainty.

Qualifications of Dr. Roberts

2. I am a Principal Scientist and Director of the Center for Occupational and Environmental Hygiene in the Chicago office of Exponent, a research and consulting company headquartered in Menlo Park, California. I have worked at Exponent since November 2003.
3. I am a physician trained in occupational medicine and epidemiology. I have expertise and training in occupational and environmental medicine as it relates to workplace and environmental exposures. I am board-certified by the American Board of Preventive Medicine in Occupational and Environmental Medicine, a Fellow of the American College of Occupational and Environmental Medicine, and a member of the College's Board of Directors since 2000. I was on the faculty of the Medical College of Wisconsin, Milwaukee, Wisconsin, where I participated in the training of medical students and physicians on issues related to occupational and environmental medicine. I have 17 years of experience in various positions at the Oklahoma State Department of Health, focusing on public health issues, and 15 years of experience in the practice of occupational and environmental medicine in various settings. I am an Associate Clinical Professor at the Institute for Health and Society, Medical College of Wisconsin, Milwaukee, Wisconsin. From 1998 to 2003, I was the Corporate Medical Director of a large company. I have also served on the Agency for Toxic Disease Registry (ATSDR) Board of Scientific Advisors. A copy of my *curriculum vitae* is included as Attachment A.
4. I earned a Master's degree in Education in 1972, a M.P.H. in Epidemiology and Biostatistics in 1974, and a Ph.D. in Epidemiology and Biostatistics in 1979. I completed medical school in 1986, and completed an internship in Family Medicine in 1987 and a Residency/Fellowship in Occupational and Environmental Medicine in 1990. I have unrestricted licenses to practice medicine in Oklahoma, Wisconsin and Illinois.
5. I have expertise in the field of epidemiology, both generally and specifically with regard to exposure to asbestos and asbestos-containing friction products and in the epidemiology of asbestos-related disease (mesothelioma, lung cancer, and asbestosis), as well as other cancers. Based on this expertise and my experience described above, I state the following.

Statement of purpose

6. The purpose of this affidavit is to explore Dr. Hammar's theory that a single asbestos fiber can cause malignant disease, specifically mesothelioma, or, alternatively, that every asbestos fiber above background can cause disease. Specifically, Dr. Hammar opined that every

occupational and bystander exposure to asbestos above background contributed to the development of Mr. Smith's mesothelioma. The issues examined in this affidavit in evaluating Dr. Hammar's theory are as follows: 1) has the theory been tested?, 2) has the methodology been peer-reviewed by the scientific community?, and 3) is the theory generally accepted in the scientific community?

7. Prior to evaluating these three issues, a basic discussion of epidemiology follows.

Epidemiology

8. Epidemiology is the study of the distribution and determinants of health events in populations (Last, 2001). The key elements of epidemiology are comparisons of health outcomes and exposures between groups, which allow for the calculation of relative risk estimates, and the careful evaluation of underlying determinants that may affect the outcome of comparisons of the study groups (bias and confounding). The scientific body of knowledge relative to a particular disease often starts with observations by clinicians, termed case reports and case series. These reports are not analytical studies because they have no comparison group or other means to test for associations. Case reports and reports of series of cases help generate scientific hypotheses; however, they cannot be used in testing for association or causation (Checkoway, 2004). Epidemiology can be used to test whether or not different exposures contribute to the risk of disease. Epidemiology also considers other aspects of science, including toxicology and exposure assessment, to determine if the results of the epidemiology studies are consistent with other scientific evidence. Consistency across epidemiology studies is a critical factor in considering associations between exposure and disease. Epidemiology is the real-life measure of outcomes of exposures in the workplace and the environment, which provide more weight than studies conducted in animals (Elmes, 1994; Hodgson and Darnton, 2000; Berman and Crump, 2003; U.S. Environmental Protection Agency [EPA], 2005; National Toxicology Program [NTP], 2011).
9. The only accepted way to prove a theory is by application of the tried-and-proven process commonly referred to as the scientific method, one of the basic tenets of scientific research. The scientific method involves formulating a hypothesis based on observations (e.g., case reports or case series) and empirically testing that hypothesis in well-designed studies with comparisons to reference populations or control groups. One of the basic premises of the scientific method is that the results are repeatable, with multiple studies reaching the same or similar conclusions, sometimes using a variety of approaches. Conclusions obtained using the scientific method should also be vetted across scientific disciplines, to ensure that the approach and study results are consistent and valid.

Has the theory been tested?

10. The theory described by Dr. Hammar that a single asbestos fiber above background can cause mesothelioma lacks scientific credibility simply because it cannot be proven. While theoretically possible, the probability of identifying the specific chain of events in an individual culminating in occult disease is infinitesimally small. Scientists do not determine causation based upon possibilities; they determine causation based upon the accumulation of

results of well-designed epidemiologic studies, in adherence to the scientific method, which show consistency across scientific disciplines.

11. In the context of the scientific method, Dr. Hammar's opinion that exposure from a single fiber above background can cause mesothelioma is a hypothesis. This hypothesis cannot be feasibly tested either in an individual or a population, as individuals are typically exposed to multiple substances and products throughout their lifetime. This is recognized not only in the scientific community, but also by regulatory agencies, who recognize that most individuals exposed to asbestos experience mixed exposures (Occupational Safety and Health Administration [OSHA], 1994). In addition, due to the long latency for development of mesothelioma (Lanphear and Buncher, 1992), it is not possible to reconstruct an individual's exposure for evaluation of a single-fiber exposure that occurred decades earlier.
12. While it is clear that animal studies should not be used when adequate human-based data is available, there are several animal studies that shed important light on the issue on Dr. Hammer's opinion regarding "every fiber counts." Animal studies clearly indicate that there are levels below which there is no observable pathological effect resulting from exposure to asbestos (e.g., Berman et al., 1995; Stettler et al., 2008).

Has the methodology been peer-reviewed by the scientific community?

13. To my knowledge, in addition to not being tested, as described above, the theory that every exposure counts in development of disease has not been subject to peer review. There are a number of opinion pieces published by scientists who have a special interest in the longevity of the "every-fiber-counts theory;" however, these opinion pieces have not been vetted nor embraced by the scientific community. These opinion pieces are not scientific research studies, but rather represent opinions of persons regarding this topic. Publishing opinion pieces or legal briefs in no way validates these opinions in the absence of peer-reviewed science-based research to support them.
14. There is no generally accepted scientific methodology that supports the conclusion that every fiber above background is causative of mesothelioma. Paracelsus, father of toxicology, taught us that to evaluate an exposure to a toxic substance, one must look at intensity, duration, and frequency, as well as type of chemical, to determine effect. As a result of his work, Paracelsus coined the phrase "The dose makes the poison," which is now a basic tenet of toxicology. Paracelsus' teaching indicates that, in the context of asbestos, issues such as a fiber type, fiber dimension, and nature of exposure should all be considered when evaluating cause-and-effect relationships, as the potency gradient differs between asbestos fiber types and sizes and health effects are dose-dependent.
15. With regard to fiber type, there are large differences in the relative carcinogenicity of different asbestos fiber types. Current evidence indicates that amphibole asbestos is significantly more potent than chrysotile asbestos in terms of causing mesothelioma (Hodgson and Darnton, 2000, 2010; ERG, 2003a; Berman and Crump, 2008a,b), with some indicating that chrysotile is not associated with mesothelioma at all (ERG, 2003a). The only commercial asbestos type found in friction products such as brake pads is chrysotile (Rosato, 1959; Sheehy et al., 1989), which is the least potent form of asbestos (Hodgson and Darnton,

2000; Eastern Research Group [ERG], 2003a,b; Yarborough, 2006; Berman and Crump, 2008a,b). The difference between chrysotile and amphiboles is also evidenced by the differences in biopersistence, or durability in the human body. Chrysotile is cleared from the lungs in a matter of days or weeks, whereas amphiboles can remain in the human lungs for years (Bernstein et al., 2005, 2010, 2011). Amphibole fibers, which contain iron as part of their make-up, are known to persist in the body and be resistant to chemical changes, sometimes forming ferruginous bodies, or dumbbell-shaped structures with an iron core (Roggli et al., 1992; Churg and Green, 1998). In contrast, the magnesium irons that form the basis of chrysotile are easily depleted in low pH conditions, and are more easily removed via the body's natural defenses (Churg and Green, 1998). This is also supported by the fact that chrysotile fiber content of the lung has little relationship to asbestos body concentrations (Case, 1994).

16. With regard to fiber size, in general, short fibers, including short asbestos fibers, have little to no disease-producing potential (Stanton et al., 1977, 1981; ERG, 2003a,b). The shortest grade fibers were typically used in molded brake linings and clutches (e.g., Clifton, 1979; Pigg, 1994), with most less than 5 μm in length (Brorby et al., 2008). Results of a 2002 ATSDR panel indicated, "panelists agreed that there is strong evidence that asbestos and short vitreous fibers shorter than 5 μm are unlikely to cause cancer in humans" based on "findings from epidemiologic studies, laboratory animal studies, and *in vitro* genotoxicity studies, combined with the lung's ability to clear short fibers" (ERG, 2003a). In general, evidence in the published literature indicates that fibers less than either 5 μm or 10 μm in length do not contribute to asbestos-related disease (ERG, 2003a,b). Thus, there are certain exposures to short-fiber asbestos to which no disease occurrence is anticipated.
17. Furthermore, the every-fiber-counts theory is flawed because it fails to address the more relevant question: Is the risk of mesothelioma increased under the circumstances of exposure that are relevant to the case at hand? Dr. Irving Selikoff, one of the forefathers of asbestos-related research, recognized that exposures in various occupational settings are different, noted "It is inadequate to speak now of 'asbestos workers.' With the growth of asbestos utilization, including rapid multiplication of the number and variety of its applications, it would perhaps be more accurate to categorize workman exposed to asbestos as 'asbestos textile workers,' 'asbestos insulation workers,' 'asbestos miners,' 'asbestos mill workers,' 'asbestos cement workers,' etc. The different occupations vary widely in important respects; in intimacy, intensity and duration of exposure, in variety and grade of asbestos used, in working conditions, in concomitant exposure to other dusts or inhalants" (Selikoff et. al. 1965). With regard to Dr. Hammar's theory, evaluation of various exposures incurred by Mr. Smith throughout his lifetime should not be treated equally. Recent studies also suggest that earlier, high-intensity exposures may be more important in disease development (La Vecchia and Boffetta, 2012; Rake et al., 2009).
18. The generally accepted scientific methodology for determining whether an asbestos exposure could be causative would be to review the available literature giving priority to the relevant studies in an evidenced-based medicine approach (Guyatt et al., 2000). With regard to Mr. Smith, his occupational history indicates that he held various jobs within his lifetime, one of which involved work as a mechanic. With regard to vehicle mechanics, there are a total of 21 epidemiologic studies that included occupational groups considered to have most likely

performed brake work or that studied the risk associated with brake work itself (McDonald and McDonald, 1980; Petersen and Milham, 1980; Teta et al., 1983; Spirtas et al., 1985, 1994; Olsen and Jensen, 1987; Järholm and Brisman, 1988; Hansen, 1989; Gustavsson et al., 1990; Woitowitz and Rödelberger, 1994; Coggon et al., 1995; Teschke et al., 1997; Agudo et al., 2000; Milham and Ossiander, 2001;¹ National Institute for Occupational Safety and Health [NIOSH], 2002; Hansen and Meersohn, 2003; Hessel et al., 2004; McElvenny et al. 2005; Rolland et al., 2010; Rake et al., 2009; Aguilar-Madrid et al., 2010; Merlo et al., 2010). Sixteen of these studies are peer-reviewed studies published in scientific journals, and five are government or institute reports. None of these studies identified an increased risk of mesothelioma due to this occupation or tasks associated with this type of work. That is, none of the studies identified a statistically-significant relative risk greater than 1.0, indicating that none of the studies identified an association between brake work or work as a vehicle mechanic and mesothelioma. These studies were conducted by different investigators, in different geographic regions, using various methods, during different time periods, and consistently show no increased risk of mesothelioma. In addition, results of the epidemiologic studies of vehicle mechanics are consistent with other scientific disciplines, such as industrial hygiene and toxicology, where exposure data indicate low average exposures to short chrysotile fibers (e.g., Anderson et al., 1973; Roberts and Zumwalde, 1982; Rödelberger et al., 1986; Blake et al., 2003; Paustenbach et al., 2003; Finley et al., 2007; Madl et al., 2009) and toxicology data indicate that the chrysotile fibers present in brakes undergo heat transformation during the process of braking (e.g., Weir and Meraz, 2001; Langer, 2003; Madl et al., 2009), with chrysotile being significantly less potent than other forms of asbestos (Hodgson and Darnton, 2000; ERG, 2003a,b; Yarbrough, 2006; Berman and Crump, 2008a,b). Langer (2003) further notes that the loss of structure and surface modifications that chrysotile in brakes undergoes during the braking process results in a reduction or loss of biological activity of the fiber. These changes start at the lower end of the range of temperatures measured in the braking process. This literature also indicates that working as a vehicle mechanic does not add to the risk of developing mesothelioma in persons exposed to asbestos in other occupations (Hessel et al., 2004). All of the studies that were available as of 2004 were reviewed for inclusion in a meta-analysis of mesothelioma among motor vehicle mechanics (Goodman et al., 2004), which indicated no increased risk of mesothelioma. The results of this meta-analysis are consistent with other reviews of the cumulative body of research on vehicle mechanic work and mesothelioma (Wong, 2001; Laden et al., 2004). Thus, the theory regarding every-exposure-counts is clearly disproven by this cumulative body of literature.

Is the theory generally accepted in the scientific community?

19. Every fiber above background inhaled does not lead to disease. If this were true, there would be far more cases of mesothelioma than we currently observe in the population, because we have all been exposed to some asbestos during our lifetimes from inhalation of ambient air and, on average, have millions of asbestos fibers in our lungs (Churg and Warnock, 1980).

¹ Milham and Ossiander (2001) is an unpublished government report discussing various results and analyses from the Washington Occupational Mortality Database (WOMD). These data were updated in 2011. The updated data and analyses from the WOMD are available on the following website:
<https://fortress.wa.gov/doh/occmort/OMQuery.aspx> (Washington Department of Health, 2011).

In fact, Dr. Hammar acknowledges the presence of a background concentration of asbestos in his opinion, stating that every occupational and bystander exposure to asbestos *above background* contributed to the risk of developing mesothelioma; thus, this implies that Dr. Hammar acknowledges a level below which asbestos exposures do not contribute to disease. In addition, the every-exposure-counts theory ignores the body's defense mechanisms, which eliminate the majority of fibers from the body. These mechanisms include, among others, mucociliary clearance and removal from the body by macrophages (ATSDR, 2001).

20. In addition to a background or ambient exposure level, there is also a background rate of mesothelioma, where the disease is unrelated to asbestos exposure and is caused either by unknown causes or occurs spontaneously (McDonald, 1985; Hillerdal, 1999; Price and Ware, 2004, 2009; Teta et al., 2008). Cancer, as a general entity, occurs as a result of unregulated cell growth and genetic mutations that begin to occur at birth. It takes multiple genetic mutations to cause cancer, with most genetic mutations being insignificant because the body either repairs the damage or the cell dies and does not lead to further mutations. The accumulation of such genetic mutations, and therefore the risk of developing cancer, including mesothelioma, increases dramatically with age (Moolgavkar et al., 2009).
21. Cancer, including mesothelioma, can occur naturally (spontaneously) without exposure to environmental agents. Given the lack asbestos exposure history in every mesothelioma case, the presence of other known causes, and other supporting evidence (e.g., cases of mesothelioma occurring in children), it is generally well-accepted in the scientific community that there is a background rate of mesothelioma (Walker et al., 1983; McDonald, 1985; Ilgren and Wagner, 1991; McDonald and McDonald, 1994; Huncharek, 2002; Price and Ware, 2004, 2009; Teta et al., 2008; Moolgavkar et al., 2009). A recent analysis of Surveillance, Epidemiology and End Results (SEER) data estimated that approximately 300 cases of mesothelioma in the U.S. annually may be unrelated to asbestos exposure (Teta et al., 2008).
22. The published literature indicates that mesothelioma is most often associated with asbestos exposure (e.g., Spirtas et al., 1994), and specifically to amphibole asbestos (e.g., Doll and Peto, 1985; Yarborough, 2006; Berman and Crump, 2008a,b), although a substantial proportion of cases report no known asbestos exposure in epidemiologic studies (e.g., Spirtas et al., 1994; Agudo et al., 2000; Rake et al., 2009). A variety of non-asbestos etiologies have been suggested (e.g., Peterson et al., 1984; Pelnar, 1988) and confirmed (e.g., Teta et al., 2007). The percentage of mesothelioma cases in the published literature with no evidence of asbestos exposure is extremely variable, ranging from 0 to 87 percent (Spirtas et al., 1994). Other known risk factors for mesothelioma include erionite, Thorotrast, and therapeutic radiation (e.g., Boffetta, 2007; Teta et al., 2007) and may explain only a small proportion of cases.
23. Plaintiff's experts often advance the notion that there is no safe level of exposure to asbestos, citing various regulatory documents to support their position. Statements by regulatory agents that there is no known safe level of asbestos do not prove that a low level of chrysotile (or any asbestos fiber type) exposure is a hazard. In addition, the contention that there is no threshold for asbestos-associated cancer is based not on direct observation, but on mathematical risk assessments conducted by regulatory agencies. In most of the analyses

published by regulatory agencies, who are charged with protecting public health from a policy perspective, a linear non-threshold model is assumed *a priori*, regardless of whether such a threshold exists (Nicholson, 1986; OSHA, 1986; Hodgson and Darnton, 2000; Berman and Crump, 2003). OSHA regulates the work environment and has set a permissible exposure level (PEL) for asbestos at 0.1 f/cc for an 8-hour work day. OSHA notes that this level poses a practical threshold equivalent to the lower limit of feasibility for reliably measuring asbestos exposures (OSHA, 1994); this does not prove that a single or very low exposure causes disease. In fact, the cumulative exposure of vehicle mechanics based on vehicle mechanic exposure data was calculated and estimated to be approximately 3 f/cc-years (Finley et al., 2007). This is lower than the theoretical 45-year cumulative exposure of 4.5 f/cc-years resulting from exposure at the current OSHA PEL of 0.1 f/cc, indicating a level of asbestos exposure (short, low level chrysotile) below which no disease is observed.


24. Contrary to Dr. Hammar's theory, every exposure does not add to measureable risk. For example, as noted above, Hessel et al. (2004) examined risks for brake work, while taking into account other asbestos-related occupations held by both cases and controls identified in the Spirtas 1994 article, based on data obtained from the National Cancer Institute. Hessel et al. observed no increased risk for either non-occupational or occupational brake work, even for long-term employment involving brake work (defined as greater than 10 years). In addition, the risks related to shipbuilding and insulation work were not different from those risks observed in insulation or shipyard workers who also did brake installation and repair, contrary to the theory that every asbestos exposure adds to the risk of mesothelioma.

Summary and conclusion

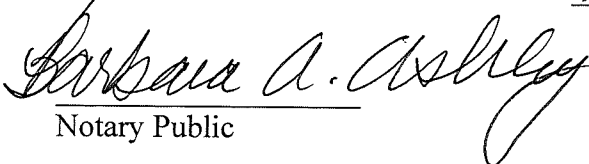
25. General causation asks whether an exposure to a substance has been associated with a disease. A key point in this discussion centers on the term "substance" in discussing causation and association. It is abundantly clear in the literature that chrysotile is chemically and physically different from amphibole asbestos, which directly affects its ability to result in disease. Causal association can only be demonstrated by repeated, well-designed epidemiologic studies using different study methods, study populations, and different times, showing consistent results that are in keeping with findings from other scientific disciplines. Association is not proven by case reports or case series nor is the summation of such cases an appropriate measure of risk since there is no indication of the true numerator of the populations that is reflected by the cases.
26. The theory that every asbestos fiber above background contributes to mesothelioma does not follow logically and is not accepted in the scientific community. The Plaintiffs' experts talk about chrysotile causing mesothelioma, but do not consider dose; they then talk about brief exposures causing mesothelioma, but do not consider the fiber type. One cannot compare low doses of one asbestos fiber type with a low risk (e.g., chrysotile), to low dose of another asbestos fiber type with a higher risk (e.g., amphibole). For example, like asbestos, ionizing radiation is a known human carcinogen. Like asbestos, different forms of ionizing radiation have different carcinogenic toxicities, with high-dose ionizing radiation being associated with an increased risk of mesothelioma (e.g., Teta et al., 2007). Like asbestos, we are all exposed to a background level of ionizing radiation in the form of x-rays and naturally

occurring radiation. Given Dr. Hammar's argument, this implies that even a single chest or dental x-ray could increase the risk of individual developing cancer.

27. While it is generally accepted that asbestos causes mesothelioma, the level and type of exposure needed to cause the disease is debated in the scientific literature. Public health and regulatory agencies have generally taken the precautionary position that all asbestos is the same and that no safe level has been identified. The precautionary principle is not constrained by the science surrounding an issue, but also includes societal aspects, regulatory and technical feasibility, and political desire. Separate regulation of chrysotile and amphiboles would be logistically and administratively burdensome, even if technically correct.
28. General causation asks whether an exposure to a substance has been associated with a disease. A key point in this discussion centers on the term "substance" in discussing causation and association. It is abundantly clear in the literature that chrysotile is chemically and physically different from amphibole asbestos, which directly affects its ability to result in development of disease.
29. In conclusion, the current science regarding chrysotile asbestos clearly indicates that it is different from the amphibole asbestos, and, in fact, may not cause mesothelioma in its pure form. In addition, scientific evidence consisting of 21 epidemiologic studies consistently indicates that vehicle mechanics, who are exposed to low levels of short-fiber chrysotile, do not have an increased risk of mesothelioma, indicating a level below of asbestos exposure below which disease does not occur.
30. For the reasons set forth above, the theory that every asbestos fiber above background can cause mesothelioma, as proposed by Dr. Hammar, has neither been proven nor accepted by the scientific community and, in fact, has been disproven by studies of occupations where no disease occurred following low levels of chrysotile exposure. There is no scientific support for the position that all asbestos exposure contributes equally to the development of mesothelioma.


MARK A. ROBERTS, M.D., ~~Ph.D.~~, M.P.H., M.Ed., F.A.C.O.E.M.

Subscribed and sworn to before me this 7th day of August, 2012.


Notary Public



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